(Court Ex. #1 (6/25/10))

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VIA EMAIL AND HAND DELIVERY

The Honorable John F. Keenan
United States District Court
Southern District of New York
500 Pearl Street, Room 1930
New York, New York 10007-1312

Re: In re Fosamax Products Liability Litigation (MDL-1789)
Boles v. Merck & Co. Inc., Case No. 1:06-cv-09455-JFK

Dear Judge Keenan:

Merck writes to request that the Court allow Merck 15 additional minutes to close prior to the Court's giving its jury charge this morning. Merck also requests that the Court specifically amend its verdict form and jury charge in the manner described herein.

Yesterday, Plaintiff's counsel intentionally and knowingly made improper and factually incorrect arguments in closing. This was done notwithstanding the Court's clear instruction to both sides the prior day that professional and respectful conduct was expected in the courtroom. Indeed, even after being admonished by the Court, outside the presence of the jury, after the improper closing argument, Plaintiff's counsel laughed and joked with members of the gallery about his closing. Continuing to allow such conduct, without any meaningful consequence, is at this stage simply encouraging such conduct.

The measures we request would provide an opportunity to attempt to restore at least a measure of balance to proceedings tainted potentially beyond repair by repeated improper argument of Plaintiff's counsel, continuing a pattern that began with improper and prejudicial questioning during trial. Moreover, without such measures, future counsel with ONJ cases may perceive that there is unfettered discretion to engage in similar objectionable and prejudicial behavior in their cases. As the Court is aware, what happened during closing statements was not an isolated instance, but rather part of a pattern of behavior. For example:

- Plaintiff's counsel brought up the *Maley* trial in front of the jury despite explicit instructions not to reference other MDL trials; (Tr. 984:13-986:10)

- The Court later had to admonish Plaintiff's counsel that "this isn't Law and Order" to "stop the sarcasm" and to not make a funny face at the Court; (Tr. 1394:2-7)

- The Court admonished Plaintiff's lead counsel off the record at the close of Court Wednesday about his co-counsel's manner during the cross-exam of Dr. Glickman; and

- The Court acknowledged on the record Plaintiff's counsel's laughter after the Court's admonishment of him late yesterday afternoon. (Tr. 1714:8-9.)

Such actions are likely to have a cumulative and prejudical effect on most if not all jurors and should not in any event be permitted. Plaintiff's counsel certainly should not be allowed to disregard clear Court orders and ignore Court admonishments with impunity.

Both requests as well as the grounds therefore are set forth below.

15 Minute Closing

As the Court recognized at the conclusion of yesterday's proceedings, Plaintiff's counsel inappropriately tried to inject punitive damages into the case and wrongly insulted Dr. DePapp. This misconduct cannot be remedied by jury instructions alone. Merck should also be given 15 additional minutes of summation to respond to Plaintiff's counsel's inappropriate arguments.

As the Court is aware, in civil trials in this district, "the order of summation shall be determined in the discretion of the court." S.D.N.Y. Local Rule 39.2. While the practice is to permit the plaintiff to go last because she has the burden of proof, the court may "deviate from this pattern in a case where the party with the final word raises an argument that could not have been anticipated," or makes a "misstatement of the record that [the defendant] should have been allowed to address." *Silivanch v. Celebrity Cruises, Inc.*, 171 F. Supp. 2d 241, 271 (S.D.N.Y. 2001). Merck cannot and should not be expected to have anticipated the substance and tenor of Plaintiff's closing, and the Court should therefore allow Merck the opportunity to have 15 minutes -- most of which Merck's counsel left in any event in its closing -- to attempt as best as possible to address Plaintiff's attacks.

While it will not be possible in these 15 minutes to address all the inaccuracies in Plaintiff's closing, Merck should at the minimum be allowed to address the purported substantive attacks interwoven with the personal attacks made on Drs. DePapp and Glickman, as well as the unfair attacks made on the FDA.

Dr. DePapp

Plaintiff stated about Dr. DePapp:

> Do you see the trick? It doesn't matter. As I was saying, the truth is a powerful thing and you can't get away from it. And so -- do you have that? Dr. de Papp's -- could you just, I know it's out of order what we planned, but I can't help myself. The quote of the doctor. I have it here. 13, lucky 13 for Dr. de Papp's slide. She said a lot of stuff. She said a lot of stuff. But I nearly fell out of my chair. If you remember, they come and they have hours of preparation, 50, 60, 70, 80 for a deposition. Who knows what they do to prepare for a trial. What takes so long? To come and tell us the truth, you know? We're not going to hurt you. We're just going to ask you questions. So all the things she said, here it is, folks, and she's not the only one to say this. "You can only say that the group with the lowest BMD and in this case that's these women who had the bone density of worse than 2.5, that's the only group" -- I should get out of your way -- "that's the only group that you can make an inference about and say that they benefited in terms of the reduction of hip and wrist fractures." That's plain English, folks. Finally, we got a little plain English. The truth came out. Somewhere in this long answer and all the testimony, the questions by Mr. Strain and the answers for which they prepared for, hours and hours, the truth -- I love the truth. You can't run from it. It comes out like Edgar Allen Poe, The Telltale Heart. Boom, boom. (Tr. 1667:22-1668:23.)

The fundamental problem with the above -- in addition to the personal attacks directed at Dr. DePapp in the manner they were -- is that there is a substantive quote mixed into the highly inflammatory statements about her testimony. This substance of course is demonstrably incorrect. While Plaintiff's counsel was pounding the screen and demonstrating to the jury sound effects from Edgar Allen Poe's poem, the jury may not have had the opportunity to notice that the sentence Dr. DePapp gave was pulled from the following answer: "When we look at the morphometric, the x-ray determined spine fractures, there was no dependence on what that patient's baseline BMD is. *They all benefited.* If we look at these other clinical fractures like hip fractures or wrist fractures, *the test for interaction actually was positive*. And in that case you cannot make assumptions about these other groups. You can only say that the group with the lowest BMD, and in this case that's these women who had the bone density of worse than 2.5, that's the only group you can make an inference about and say that they benefited in terms of the reduction of hip and wrist fractures. *But the point is that there was clear benefit, even for the women without osteoporosis in terms of vertebral fractures.*" (Tr. 1115:19-21.) The quote Plaintiff excerpted is given no more than passing reference in the above riff, likely because it is so dramatically taken out of context.

The above example is simply demonstrative; Dr. DePapp was mentioned in excess of 10 times in Plaintiff's closing, in addition to the numerous times she was referred to as that woman or simply by pointing at Dr. DePapp that was not captured on the transcript. At one point, Dr. DePapp's professional career was made light of -- with obvious participation from certain members of the gallery -- with a nonsensical attack: "But she can diagnose fractures riding the subway. Is it the A train? Or is it the number 4 train? Is it going uptown? Or is it going

downtown? Is it in Russia? Do you have to have your coat on? Don't you have to take your coat off?" (Tr . 1688:21-25.)

Dr. Glickman

Similarly, Plaintiff's counsel inaccurately described Dr. Glickman as being part of a "dog and pony show" who was "reading from the board" and who Plaintiff's counsel "would bet you dollars to doughnuts that he didn't read those medical records." (Tr. 1671:7; 1672:3-4.) This statement of counsel's opinion unsupported by any testimony or other evidence continued an improper tactic begun during cross-examination. Plaintiff's counsel also several times accused Dr. Glickman of "being defensive," even though the Court had admonished against this mischaracterization during cross. (Tr. 1336:10-14; 1672:1, 2, 12; 1673:2.) And, as with Dr. DePapp, mixed into this were misstatements about Dr. Glickman and his testimony.

> I want to see if there's really evidence of osteomyelitis. When did she first have osteomyelitis, Doctor, not what your fancy flash cards say. Let's look. There's a history in the record of chronic infection, she's infected in her mouth, bugs are flying out. That's the impression you get. But, no, look at the medical records. Was that in the medical records? I don't think that was in the medical records. Did anybody see that? So I asked him, what do you got there, because I want to find this incredible raging infection that you're leading this jury to believe with your fancy flash cards. What did he say? That's a ridiculous question. Okay. I'm just trying to -- I want to know what -- you know, like he didn't even -- I'm not even sure he read the records and that's when he got defensive. I know we're fooling around with it and I'm making fun. But why is he so defensive? (Tr. 1671:11-1672:2.)

FDA

Plaintiff's attacks on FDA began with an inappropriate Hurricane Katrina reference:

> You know, God bless America. Love her. Fight for her. Die for her. We're not perfect. And it's no shock. To think that the FDA is not perfect? Oh, my goodness. Of course Merck will tell you they're perfect because they want you to think once we get approval, that's it. But I just have two words to say to you, folks, when you think of our federal government sometimes. And say God bless America. Because here we can talk about it. And we can criticize so that we get better. Hurricane Katrina. Okay. (Tr. 1681:16-25)

From there, Plaintiff's counsel described FDA as having an "incestuous" relationship with pharmaceutical companies, described "the whole department of FDA" as being "funded by industry," and inaccurately stated that "in exchange for this funding, they have a time limit to approve the drug." (Tr. 1669:15; 1682:3; 1669:10-11, 16-17.) Plaintiff's attacks on FDA continued in this vein, with little or any connection to its consideration or oversight of Fosamax.

Plaintiff's counsel's attacks on the FDA and its powers and resources were a repeat of what the Court *did not allow* Plaintiff to do during numerous attempts to introduce purported general attack on the FDA-type evidence during Plaintiff's direct questioning of Dr. Parisian. While Merck believes it is important for the Court to review Plaintiff's counsel's efforts in this regard, because of the sheer length of the relevant exchange Merck has included the text as Appendix A. In fact, what is attached at Appendix A is just a partial passage from Plaintiff's counsel's attempts to introduce general non-Fosamax specific testimony through the IOM report -- and incidentally includes a reference to Vioxx, which the Court had also held excluded -- which concludes with the Court's admonition that "We're not going to get into government funding here. That has nothing to do with this case." (Tr. 919:1-3.)

The Court's admonition regarding government funding not being a part of the case was so blatantly disregarded during closing arguments that these comments standing alone constitute an affront to justice:

- "Heck, Judge Keenan said taxes pay for it. Didn't turn out that way. Isn't that an interesting thing how incestuous that is?" (Tr. 1669:13-15);

- "We learned a few days ago, last week, whenever it was, that the FDA is funded by in part the industry in exchange for early approvals." (Tr. 1680:13-16)

- "In exchange for the funding they have a time limit to approve the drug, ten to twelve months. Remember that?" (1669:16-17)

- "Is it a shock to us here in 2010 that the FDA is not perfect? Is it an eye-opener that we learn that they're funded in part by the industry that's a semi-incestuous situation?" (1682:1-3)

Finally with respect to the FDA, Plaintiff's counsel also attempted to confuse the issues by suggesting to the jury that the Mucci review somehow postdated the approvals: "This is crazy talk, Dr. Mucci, who realized after approval that it doesn't work." (Tr. 1692:20-22.) "This is what Mucci discovered later on when you break it down. Holy Moly. Now it's too late. It's on the market. Approval. They have no power." (Tr. 1697:18-20.) However, as the jury may or may not recall, the Mucci review is dated September 1998. Mr. Mucci was reviewing the FIT II data. The FIT II date was first approved by the FDA in the label in November 1999 -- 14 months after this.

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This Court has already found in dismissing the punitives aspect of this case that "[n]o jury could reasonably find by clear and convincing evidence that Merck's actions were so 'reckless or wanting in care that it constituted a conscious disregard to the life, safety, or rights of persons' treated with Fosamax." (Summary J. Op. & Order at 41, Aug. 5, 2009.) For all of the above reasons, the Court can and should allow Merck the opportunity to attempt as best it can to level the playing field before this case is submitted to the jury with fifteen additional minutes

of argument, which will focus primarily on the above three topics, but will also try and undo some of the damage done by the following additional remarks of counsel:

- *AIDS* (1710:2-12)

  When it comes to -- they like to say, oh, it's osteomyelitis that came before this. I want you to think about a lot of diseases have sequalae. You know, lung cancer, it's an injury and it causes other things to happen to you. Unfortunately, AIDS is a horrible thing, but it has all kinds of other symptoms that it produces. But they want you to think that the symptom is her disease and not the AIDS. It's the same analogy. She has osteomyelitis because of ONJ, not the other way around. And she's suffered enough. And we ask you to give her a little justice, to say something to Merck, that it stops here.

- *Charitable Donations* (1686:2-6; 1686:7-9)

  a. And by the way, it does turn out they're paying their experts, didn't it? Dr. Bilezikian says he gives it to charity. I hope he does. In his name.

  b. And Dr. Glickman, finally, day two he remembered how many hours. He couldn't remember how many hours he put in and bills for at five hundred dollars an hour. Says he gives it to the hospital. I hope he does. That's what he says.

- *Fosamax Jingle* (1683:10-16)

  Well, where can I get some Fosamax? Fosamax, Fosamax every day. Take one every day and keep your brittle bones away. I can just hear the theme song right now as he was saying.

Jury Instruction And Verdict Form

Merck also requests that the Court revise its jury charge and verdict sheet in order to ensure that misstatements by Plaintiff's counsel do not mislead the jury as to the appropriate standards to be applied in this case.

Foreseeability and risk/benefit test.

Plaintiff's counsel implied to the jury that Merck's alleged knowledge about ONJ in 2004 and 2005 are relevant to Plaintiff's design defect claims *See* Tr. 1704:20 ("They knew it in 2004); 1705:7-8 ("That's in 2005"). But, the issue on both of the design defect claims is what was foreseeable to Merck prior to October 2003.

Plaintiff's counsel also told the jury that the risk/benefit analysis should consider only women with T-scores of between -2.0 and -2.5. *See* Tr. 1678:23-24 ("This medicine is defectively designed for women who have her T-scores."); *id.* at 1691:23-1692:2("Fosamax is unreasonably dangerous. No fracture decrease benefit in women with T-score between – that's the key – 2.0 to 2.5 . . . That's our claim. 2.5 and worse, it's a great drug. Give it to them.").

But, that is also incorrect. *See Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999) ("The defectiveness of a design is determined based on an objective standard, not from the viewpoint of any specific user."); *Ramos v. Simon-Ro Corp.*, 2008 WL 4210487, *8 n.12 (S.D.N.Y. Sept. 11, 2008) (when applying risk/benefit test, fact finder is to consider, among other things, "the product's utility to the public as a whole").

It is fundamentally unfair to permit the jury to deliberate on this case without correcting Plaintiff's counsel's misstatements as to the applicable legal standards. Therefore, Merck asks that the Court correct these misstatements by doing the following:

1. Revising questions 1 and 2 on the verdict form at minimum to include a reference to "the Fosamax Plaintiff took prior to September 30, 2003" as being the allegedly defective product.

2. Revising question 1 on the verdict form to state: "Do you find that the Fosamax Plaintiff took prior to September 30, 2003 was defectively designed in that it presented a foreseeable risk of ONJ that outweighed its benefits to patients for whom it is prescribed, and that its defective design was a legal cause of Plaintiff's injury?"

3. Revising question 2 on the verdict form to state: "Do you find that Merck breached a duty to Plaintiff to use reasonable care with respect to the design of the Fosamax Plaintiff took prior to September 30, 2003, and that Fosamax had a defective design that was a legal cause of Plaintiff's injury?

4. Revising the second sentence on page 22 of the jury charge as follows: "A prescription drug is 'unreasonably dangerous' if the risks of the drug outweigh its benefits to the patient population for whom it is prescribed."

5. Adding the following language at the end of page 23 of the jury charge: "You may not find that Fosamax was defective if it did not present a foreseeable risk of ONJ before October 2003."

Punitive damages

As the Court observed after yesterday's summations, "It's clear that what was being said [by Plaintiff's counsel] was an effort to inject punitive damages into the case, which was clearly improper." (Tr. 1713:8-11). The Court added that "my charge tells the jury what the contentions are." (*Id.* at 24:25.) However, Merck respectfully submits that a curative instruction, and not just the Court's standard damages instruction, is needed to ensure that the jury does not render a punitive verdict. Merck suggests the following language be added to the jury charge before the concluding instructions at page 40:

> One final word about damages. During yesterday's summation, Plaintiff's counsel urged you to render a damages verdict that would "say something to Merck." In other words, Plaintiff's counsel urged you to render a verdict that would punish Merck. Plaintiff's counsel's argument was inconsistent with the law, and thus inappropriate. If you decide to render a

damages verdict for Plaintiff, that verdict should not be aimed at punishing Merck or "sending a message" to Merck, or to anyone else. The purpose of any damages award you may render should be solely to compensate Plaintiff for her injury.

Respectfully submitted,

cc: Timothy M. O'Brien, Esq.
Gary J. Douglas, Esq.
David J. Heubeck, Esq.

APPENDIX A

The entire exchange discussed in the text of the letter actually covers *nine* whole pages of the transcript. Dr. Parisian's background and other non-Fosamax specific testimony cover the majority of the Plaintiff's direct examination. In contrast, Plaintiff's actual opinions regarding Fosamax cover just thirteen pages of the transcript (919-931), consisting primarily of sustained objections and inaccurate descriptions of the federal regulations on which Dr. Parisian has been called as an expert. *Contrast* Tr. 926:10-12 ("Again, that would be your 21 CFR 314.80B. *You're required to evaluate, to investigate, to test*, and so it's a requirement of pharmacovigilance.) *with* 21 CFR 314.80B ("[The manufacturer] shall also develop written procedures for the *surveillance, receipt, evaluation, and reporting* of postmarketing adverse drug experiences to FDA.") (Emphasis supplied). Below is the portion of the exchange relevant to the general FDA funding issues that was heard by the jury *after* the parties had discussed the issues at sidebar.

MR. STRAIN: Objection. Objection. Excuse me, Doctor. Objection on relevance, your Honor. The book should speak for itself.

THE COURT: Does this have anything to do with Fosamax specifically, this document?

THE WITNESS: No, sir.

THE COURT: No?

THE WITNESS: Yes, sir.

THE COURT: Does it have anything to do with Merck specifically?

THE WITNESS: Yes. Indirectly.

THE COURT: Indirectly.

THE WITNESS: Yes, sir.

THE COURT: But not specifically.

THE WITNESS: I haven't looked to see specifically if one of Merck's products is in there.

THE COURT: You haven't looked at this?

THE WITNESS: I have looked at the document. I haven't looked for one specific drug name. I believe it occurs in there.

THE COURT: You were concerned in this case concerning Fosamax and Merck, right?

THE WITNESS: Yes, sir.

THE COURT: Is Merck in the document?

THE WITNESS: I believe the word "Vioxx" is in the document.

THE COURT: The word "Vioxx." That's the heart drug?

THE WITNESS: No, sir. That's the antiinflammatory drug for heart issues.
THE COURT: That's the antiinflammatory drug that allegedly caused other problems. That has nothing to do with Fosamax.

THE WITNESS: No, sir.

THE COURT: I'm going to sustain the objection. This has nothing to do with --

MR. DOUGLAS: Your Honor it has to do with --

THE COURT: I'm sustaining the objection. The witness said it has nothing to do with Fosamax.

MR. STRAIN: It's still on the screen.

MR. DOUGLAS: Your Honor, if I may be heard briefly on what our offer of proof is on this and what it's relevant to.

MR. STRAIN: May I just interrupt? With respect to your ruling, I think it should be taken down, your Honor.

THE COURT: If it has nothing to do with Fosamax, I'm sustaining the objection. I want to limit this case to Fosamax. I want to move the case along. Next question.

MR. DOUGLAS: Your Honor, it has to do with the resources of the FDA and what they have the power to do or should I say not do.

THE COURT: The FDA controls aspirin. The case has nothing to do with aspirin. The FDA controls Vioxx. The case has nothing to do with Vioxx.

MR. DOUGLAS: And Fosamax, and this has to do with what powers they have or don't have or what resources they have or don't have and what they do or don't do specifically.

THE COURT: Put another we question. I'm not taking anything that doesn't have anything to do with our case.

MR. DOUGLAS: If I may lay a foundation for it, your Honor.

Q. Does this book have --

THE COURT: You will follow my directions. Now, look, we have enough documents in this case to fill the whole jury room if 803.18 permitted the documents to go in.

MR. DOUGLAS: I understand, your Honor. I felt it would have been helpful to the jurors to know about resources the FDA has --

THE COURT: Limit it to what she's allowed to testify to and concerning the drug in question.

BY MR. DOUGLAS:

Q. Dr. Parisian, is the drug in question regulated by the FDA?

A. Yes, sir.

Q. Is this book about the FDA and its regulatory powers?

A. Yes, sir.

Q. And would it therefore be relevant in understanding what powers the FDA has or doesn't have -- would this book be relevant to those issues?

MR. STRAIN: Objection, your Honor. The relevance is for the Court to determine.

THE COURT: I'm the one who decides what's relevant, with all due regard to Dr. Parisian. Sustained.

Q. Are you aware of what the Institutes of Medicine have said with respect to funding and/or resources that the FDA has to carry out its mission?

MR. STRAIN: Objection, your Honor.

THE COURT: Oh, sustained. We're not going to get into government funding here. That has nothing to do with this case."

(Tr. 915:17 - 919:3.)